

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIOGEN INTERNATIONAL GMBH)	
and BIOGEN MA INC.,)	
)	
Plaintiffs,)	
)	C.A. No. 17-823-LPS
v.)	(Consolidated)
)	
AMNEAL PHARMACEUTICALS LLC,)	C.A. No. 17-954-LPS
)	
Defendant.)	
_____)	

STIPULATION OF INFRINGEMENT BY ZYDUS

WHEREAS Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, “Biogen”) assert that Defendant Zydus Pharmaceuticals (USA) Inc. (“Zydus”) infringes claims 1-4, 6, 8-13, 15, and 16 of U.S. Patent No. 8,399,514 (“the ’514 patent”) (collectively, the “Asserted Claims” of the “Asserted Patent”) by submitting, or causing to be submitted, Abbreviated New Drug Application No. 210538 (“Zydus’s ANDA”) seeking approval to engage in the commercial manufacture, use, import, sale, or offer to sell Zydus’s generic capsules containing dimethyl fumarate (“Zydus’s ANDA Products”);

WHEREAS claims 5, 7, 14, and 17-20 of the Asserted Patent have not been asserted;

WHEREAS, Zydus’s ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion, the Asserted Patent is invalid or would not be infringed by the commercial manufacture, use, or sale of Zydus’s ANDA Products;

WHEREAS, Zydus denies that the commercial marketing and sale of Zydus’s ANDA Products would infringe any valid and enforceable claims asserted in this case but desires to streamline the issues at trial;

NOW THEREFORE, Biogen and Zydus, by their undersigned counsel, STIPULATE as follows:

1. For purposes of this Action only, Zydus stipulates that its submission of ANDA No. 210538 constitutes infringement of the Asserted Claims pursuant to 35 U.S.C.

§ 271(e)(2)(A), provided those claims are not proven invalid or unenforceable.

2. By entering into this Stipulation, Zydus does not waive any invalidity defenses it has raised. This Stipulation shall not be used to argue that claims satisfy the definiteness requirements of 35 U.S.C. § 112, or for any other purpose other than the issue of infringement. This Stipulation may not be used or admitted in any proceeding other than the instant proceeding against Zydus concerning ANDA No. 210538.

3. The parties reserve all other claims and defenses.

IT IS HEREBY STIPULATED:

Dated: November 8, 2019

ASHBY & GEDDES

/s/ Steven J. Balick

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*Attorneys for Defendant Zydus
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SO ORDERED, this _____ day of _____, 2019.

Chief Judge